I. Definitions

- A. Perimenopause the interval of approximately 5-10 years that precedes and follows the last menses. It is characterized by fluctuating ovarian estrogen production secondary to decreased ovarian function. This transition may be relatively asymptomatic or can be associated with a wide variety of symptoms.
- B. Menopause the cessation of ovarian function evidenced by the cessation of menses for a period of one year. Menopause may be induced surgically (oophorectomy) or medically (chemotherapy or radiation treatment). The average age of menopause in the United States is 51. Smokers reach menopause 1.5 years earlier than non-smokers.
- C. Premature menopause/ovarian failure Ovarian failure prior to age 40 resulting in cessation of menses and associated signs and symptoms of menopause.

II. Perimenopausal / Menopausal Signs and Symptoms

The signs and symptoms associated with the perimenopausal period are primarily due to estrogen deficiency (and/or wide swings in estrogen levels) and can include:

- A. Hot flashes or flushes
- B. Insomnia / night sweats/poor quality sleep leading to fatigue
- C. Mood changes
- D. Memory loss / difficulty concentrating
- E. Irregular menses, vaginal bleeding / spotting
- F. Anxiety / depression
- **G.** Vaginal/vulvar itching, pain or dryness, atrophic vaginitis (usually a late sign)
- H. Urinary frequency, urgency, urinary incontinence
- Dyspareunia, decreased libido
- J. Loss of bone density/osteoporosis
- **III. Assessment/Examination** Services and supplies for menopausal women are not required by Title X and do not have to be offered. The sliding fee scale does not have to be applied.
 - A. Comprehensive History obtain a complete personal and family history including medical/surgical, family history of osteoporosis or hip fracture, personal history of hip fracture, Ob/Gyn including menstrual, sexual, and contraceptive history, psychosocial history including lifestyle issues relative to nutrition, substance use, and domestic violence.
 - B. Physical Exam complete
 - C. Laboratory / Screening Tests
 - 1. Pap smear annually or as indicated
 - 2. Fasting lipid screen (total cholesterol, HDL, LDL, triglycerides) every 5 years if normal,

otherwise every 3 years.

- 3. Pregnancy test, if indicated
- 4. Serum FSH An FSH is an expensive test. Symptoms are usually more reliable.

 Treatment, if indicated, can be started without drawing an FSH unless the client is <40 years old. If an FSH is drawn, it should be drawn on Day 3 of the menstrual cycle.
- Baseline mammogram or negative mammogram result is recommended prior to initiation of hormone replacement. HRT may be started and a mammogram ordered within 3 months.
- 6. Hemoccult in office or fecal occult blood testing annually after age 50 or younger if risk factors are present. Sigmoidoscopy or colonoscopy at age 50.
- 7. FBS should be considered in all clients ≥ age 45. If normal, repeat every 3 years.
- 8. Endometrial biopsy or ultrasound assessment of the endometrial thickness as indicated for irregular bleeding.
- 9. Bone mineral density (BMD) depending on age and risk factors.

IV. Diagnosis

The diagnosis is usually made presumptively on the basis of amenorrhea (at least 12 months) and/or presence of menopausal symptoms in a woman at least 40 years of age.

V. Treatment Alternatives

In July 2002, the Women's Health Initiative announced that it was ceasing the estrogen/progesterone trial (women with an intact uterus) because researchers found the therapy's risks outweighed its benefits. While the HRT users in the study did have a reduced risk of colorectal cancer and fractures (including hip fractures), they also experienced more strokes, heart attacks, blood clots, and an increased risk of invasive breast cancer. The estrogen alone treatment arm was stopped in March 2004. This arm of the study also showed an increase in the rate of strokes and deep vein thrombosis, no increase in the rate of breast or colo-rectal cancer, and a reduction in the risk of hip and other fractures.

Use of HRT should not be recommended for long-term treatment to prevent cardiovascular disease. Benefits may outweigh the risks for short-term relief of vasomotor symptoms. She should take the lowest dose necessary to relieve the symptoms.

- A. Hormone Replacement Therapy (HRT)
 - 1. Precautions
 - a. Known or suspected pregnancy
 - b. Unexplained and/or undiagnosed vaginal bleeding
 - c. Active/recent thrombophlebitis or history of estrogen-related thromboembolic disease pertinent to ethinyl estradiol containing preparations, NOT the usual dose of Premarin.

- d. Active liver disease, liver dysfunction the transdermal estrogen patch can be used
- e. Women with a history of malignant melanoma must have a consultation with an oncologist/dermatologist prior to receiving HRT
- f. History of breast or reproductive cancers

Note: HRT is not contraindicated in women with hypertension, fibroids, diabetes, migraines, and/or varicosities.

Side Effects

- a. GI N/V, bloating, abdominal cramping
- b. Breast tenderness, enlargement
- c. Vaginal bleeding/spotting
- d. Weight gain/changes
- e. Acne
- f. Hirsutism
- g. Depression
- h. Insomnia

3. Risks

- a. Slight increase in the rate of breast cancer in women using HRT continuously for 5 years or more. Investigations into this association continue.
- b. Slight increase in rate of cardiovascular incidents within the first 5 years.
- c. Increased risk of endometrial cancer if estrogen is taken alone in the presence of an intact uterus. The addition of progestin decreases this risk.
- 4. Benefits HRT provides protection against bone loss and osteoporosis and relieves vaginal and urogenital symptoms at doses of 0.625 mg or equivalent.
- Recommended Regimens

The following HRT regimens are recommended for clients with an intact uterus:

You may want to consider an increased emphasis on prescribing regimens formulated with progestins other than medroxyprogesterone acetate, such as norethindrone acetate or norgestimate

a. Continuous Combined Regimen

Estrogen and progestin/progesterone daily.

(1) Withdrawal bleeding and spotting may occur for the first 6-12 months.

However, many women on continuous HRT experience amenorrhea within 6 months - 1 year.

(2) Any woman with risk factors for hyperplasia (diabetic, hypertensive, history of taking unopposed estrogen) or any woman with bleeding that persists for 12 months, should receive an ultrasound evaluation of endometrial thickness or an endometrial biopsy. If the endometrial stripe is >5mm on ultrasound, an endometrial biopsy is indicated.

b. Three-month sequential

Estrogen daily and progestin/progesterone added q 3 months for 14 days.

- (1) Withdrawal bleeding occurs every 3 months at a predictable time, although it can be heavier than monthly bleeding. Less exposure to progestin/progesterone on this regimen may lead to fewer side effects and less adverse effects on HDL.
- (2) The risk of endometrial hyperplasia does not appear to be increased, but this regimen is less well studied.

c. Cyclic Regimen

Daily estrogen **plus** progestin/progesterone for the first 14 days of every month.

- (1) withdrawal bleeding can be expected during or after the completion of the progestin cycle, although some women experience very light or no bleeding.
- (2) many clinicians start perimenopausal/newly menopausal women on a cyclic regimen, switching later to the continuous combined regimen.
- d. Estrogen only, with *intact* uterus requires yearly endometrial biopsy or ultrasound evaluation of endometrial thickness.

Equivalent Doses of Estrogens

Brand Name	Dosage
Premarin	0.625 mg
Estradiol	1.0 mg
Estratab	0.625 mg
Ogen	0.625 mg
Vivelle or Estraderm Patch	0.05 mg

6. Other Regimens

a. Post-hysterectomy/oophorectomy - Estrogen daily. Women with prior endometriosis with remaining endometriotic implants should consider adding

progestin/progesterone

- b. Women unable to tolerate estrogen because of side effects or impaired liver function Transdermal delivery, with or without progestin/progesterone, may be preferred. Estraderm 0.05 0.10 mg patch or Vivelle patch applied twice per week and Provera (or equivalent) as indicated (if uterus in situ).
- c. Women experiencing urogenital sx only Estring®/Estrogen vaginal cream 2-4g intravaginally (1 applicatorful qd) as indicated, or Vagifem® vaginal tablets 1 tablet intravaginally qd X 2 weeks followed by maintenance of 1 tablet intravaginally twice a week. Consideration may be given to providing progestin/progesterone if the uterus is in situ. All bleeding should be investigated with endometrial biopsy or ultrasound of the endometrial stripe.

7. Follow Up

- a. The first follow up visit should be scheduled in 3 months to include:
 - (1) Assessment of symptom relief
 - (2) Evaluation of side effects reassurance about bleeding, unless it has persisted for 12 months or more.
- b. Annual examinations
- B. Low dose oral contraceptives are effective in controlling perimenopausal symptoms and reestablishing cycle control in women with fluctuating levels of estrogen.
- C. Non-hormonal Options
 - 1. Herbal herbal remedies are not regulated by the FDA, so safety and efficacy information is not readily available.
 - 2. Artificial lubrication for control of vaginal symptoms and dryness.

VI. Counseling and Education

- A. Discuss the normalcy of menopause, normal changes in body systems and sexuality associated with aging.
- B. Discuss the importance of good nutrition and adequate calcium intake (1500 mg qd if not on HRT; 1200mg if on HRT). Calcium carbonate and calcium citrate are better absorbed than some other calcium formulations.
- C. Encourage regular exercise weight-bearing exercise enhances bone density.
- D. Promote a healthy lifestyle
 - 1. Decrease caffeine and alcohol consumption.
 - 2. Stop smoking.
- E. Counsel regarding the need for preventive health screening, such as Pap smear screening according to ACS guidelines, SBE, annual clinical breast exam, mammography, bone mineral

- density, and colonoscopy.
- F. Discuss importance of recommended immunizations, such as tetanus-diphtheria booster every 10 years, influenza immunization yearly after age 65 and pneumovax at age 65.
- G. Counsel re: contraception if client has not experienced cessation of menses for 1 year. Hormone levels on HRT are NOT adequate for contraception. (Hormone levels in HRT are 1/6 the levels of a pill containing 20 mcg of estrogen.)
- H. Discuss issues pertinent to STD & HIV prevention as indicated.
- I. Discuss treatment options for menopausal symptoms, refer to community and other supportive resources.
 - 1. Client risk factors for osteoporosis, cardiovascular disease, breast cancer and other family history
 - 2. Risks and benefits of HRT and alternative treatments
 - 3. Client expectations/attitudes about menopause and treatment including HRT